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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/491,982	01/27/2000	Stephen Shaughnessy	MDSP-P02-180	9313

28120 7590 11/19/2004

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/491,982

Applicant(s)

SHAUGHNESSY ET AL.

Examiner

Prema M Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/29/04
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 14, 43-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 14, 43-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/29/2004 has been entered.

2. Amended claims 1, 3 (9/29/2004) and previously presented claims 14, 43-50, are pending and under consideration by the Examiner.

Claim rejections-35 USC § 112, second paragraph

3. Claims 1, 3, 14, 43-50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the term "characterized" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 3, 14, 43-50 are rejected as vague and indefinite insofar as they depend on the above rejected claims for their limitations.

Claim Rejections - 35 USC § 103

4. Claims 1, 3, 14, 43-49 are rejected under 35 U.S.C. 103 as being unpatentable over Girasole et al (1995) in view of Kishimoto et al. (US Patent No. 5,888,510).

This rejection is maintained for reasons of record set forth at pages 2-4 of the previous Office action (3/18/04) and pages 2-4 of the Office action (5/25/04).

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Applicants argue that unlike rheumatoid arthritis, bone density is controlled *in vivo* by two types of counter-acting cells, osteoclast and osteoblast and that the *in vitro* results of Girasole only teaches the effect of IL-11 signaling on osteoclast, but is completely silent about its effect on osteoblast. Applicants argue that more importantly, the reference is completely silent about the unexpected discovery that IL-11 signalling has opposite effects in osteoclast and osteoblast *in vivo*, e.g., inhibiting IL-11 function simultaneously inhibits osteoclast function and enhances osteoblast function. However, contrary to Applicants arguments, this property of IL-11 signaling is inherent in the prior art process i.e. *in vivo* there is a balancing process and inhibiting IL-11 function would simultaneously inhibit osteoclast function and enhance osteoblast function. It is old and well known that calcification *in vivo* is in an equilibrium, synergistic state because of the constantly occurring catabolic and anabolic processes i.e. mineralization and demineralization processes. Applicants are arguing both sides of the coin. Applicants assert that the Girasole reference teaches *in vitro* the effect of IL-11 signaling on osteoclast but fails to teach promoting osteoblast function i.e. increasing bone density. However, contrary to Applicants arguments, if these effects were taught in the Girasole reference the instant rejection would be a 35 USC 102(b) rejection rather than a 35 USC 103 rejection. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

The declaration under 37 CFR 1.132 by Dr. Shaughnessy filed 9/29/2004 is insufficient to overcome the rejection of claims 1, 3, 14, 43-49, based upon 35 U.S.C. 103 as set forth in the last Office action.

The declaration is non-persuasive because it reiterates Applicants' arguments regarding the results that treatment with an anti-IL-11 antibody has the synergistic effect of both enhancing bone formation and decreasing bone resorption, which arguments have been addressed in the Office action filed on 3/18/2004 and 5/25/2004.

5. Claim 50 is rejected under 35 U.S.C. 103 as being unpatentable over Girasole et al (1995) in view of Kishimoto et al. (US Patent No. 5,888,510) as applied to claims 1, 3, 14, 43-49 above, and further in view of Queen et al. (US Patent No. 5,530,101).

This rejection is maintained for reasons of record set forth at pages 4-5 of the previous Office action (3/18/04) and pages 24 of the Office action (5/25/2004).

Applicants argue that the claimed invention is not obvious in view of Girasole et al (1995) in view of Kishimoto et al., and further of Queen et al. does not in any way correct these defects. However, as argued previously, this rejection is a 35 U.S.C. 103 rejection not a 35 USC 102 rejection. Therefore, a skilled artisan, from the combined teachings of the prior art would have an expectation of success knowing that a method of administering a humanized monoclonal IL-11 antibody to a patient would increase osteoblast-mediated bone formation process and decrease osteoclast-mediated bone resorption process since these processes are in a constant balance.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

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Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
November 15, 2004